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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/237,605  | 01/25/1999  | RICHARD J. LAZZARA   | IMPI.035-I          | 7280             |
| 30223   | 7590        | 10/07/2003           | EXAMINER            |                  |
| JENKENS & GILCHRIST, P.C.<br>225 WEST WASHINGTON<br>SUITE 2600<br>CHICAGO, IL 60606 |             |                      | PREBILIC, PAUL B    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3738                |                  |
| DATE MAILED: 10/07/2003   |             |                      |                     |                  |

50

Please find below and/or attached an Office communication concerning this application or proceeding.

|                             |                 |                |
|-----------------------------|-----------------|----------------|
| <b>Offic Action Summary</b> | Application No. | Applicant(s)   |
|                             | 09/237,605      | LAZZARA ET AL. |
| Examiner                    | Art Unit        |                |
| Paul B. Prebilic            | 3738            |                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 July 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-25,27-32,35-49 and 51-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11-25, 27-32, 35-49, ande 51-59 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-25, 27-32, 35-49, and 51-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "substantially" or "substantially uniform array of irregularities" to described the degree to which the native oxide layer is removed or the uniformity of the roughness lacks original support and/or there is no guidance as to its affect on the metes and bounds of the claim language. Since there is no guidance in the original specification, it appears that even a bulk etched metal implant surface would be substantially uniform in roughness and substantially free of the native oxide layer. Moreover, "substantially" is a broad term. *In re Nehrenberg*, 126 USPQ 383 (CCPA 1960) and see MPEP 2173.05(b) which is incorporated herein by reference. The specification fails to provide some standard for measuring that degree. Therefore, one of ordinary skill would not know what degree of roughness or native oxide layer would fall within the claim scope and what would not. The controlling case law appears to be that of *In re Mattison*, 184 USPQ 383 (CCPA 1960). It states:

We are not persuaded by the board's reasoning that one skilled in the art would not be able to determine the scope of the claimed invention in terms

of a specified percentage value. General guidelines are disclosed for a proper choice of the substituent Ep together with a representative number of examples. (emphasis added here)

The Board of Appeals was reversed because there were general guidelines as to what constituted a substantial increase. This is not the situation here where there are no guidelines in the specification, and the prior art does not give one a clear picture as to what constitutes a substantially uniform roughness or a surface substantially free of native oxide and what does not. This is a critical and defining limitation of the claim and it must be clear as to what falls within its scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-25, 27-32, 35-49, and 51-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claims is indefinite because of the ambiguity presented by the "substantially" terminology discussed in the 35 USC 112, first paragraph rejection.

#### ***Claim Rejections Based Upon Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3738

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16, 22-25, 27-33, 35-49, and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki et al (the translation of Japanese patent JP3146679A2) in view of Krueger (US 4,826,434). Haruyuki discloses an acid etched titanium implant surface with recesses having average depths of 0.5 to 5 microns; see the abstract and the "Technical Field" paragraph on page 2. Haruyuki discloses making dental repair and biorepair members including bone fixation devices and artificial dental roots, but fails to disclose implants made with threads as claimed. However, Krueger teaches that it was known to make dental implants with treaded surfaces in order to sufficiently anchor the device into the bone. Hence, it is the Examiner position that it would have been obvious to put threads on the Haruyuki dental implants in order to allow them to be securely and quickly inserted into a bone hole without sliding out therefrom.

With regard to claims 12, 25, 28, 38, 46, 47, and 54-59, the Examiner posits that since a similar type of etching process is used to form irregularities on the surface of the same material as claimed that the surface irregularities of Krueger would inherently be

the same as those set forth in the claims; i.e. cone-shaped and/or spaced about the prescribed distance.

Furthermore, upon review of Exhibit 1 and Exhibit B, Comparative Example 2 of the Dr. Gubbi declaration filed June 30, 2003, the Examiner concluded that the prior art treatments do result in cone-shaped elements; see the micrographs thereof and compare to the micrographs of Exhibit A.

With regard to claims 13 and 36, the Examiner posits that the claimed process steps result in the same invention such that the claimed invention is at least clearly obvious in view thereof. The Examiner is also under a lesser burden to show that process limitations in product claims are met; see MPEP 2113, which is incorporated into this Office action by reference thereto.

Claims 17-21 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki and Krueger as applied to claims 11-16, 22-25, 27-33, 35-49, and 54-59 above, and further in view of Niznick (US 5,571,017). Haruyuki renders obvious the claim language as set forth in the above rejection but fails to teach both a roughened region and an unroughened or other region as required by the claims. Niznick teaches that it was known in the art to have different regions of roughness where the roughened portion begins below the top surface; see Figure 1 and column 2, line 66 to column 3, line 24. Hence, it is the Examiner's position that it would have been obvious to have a smoother head portion in the Haruyuki invention for the same reasons that Niznick has the same.

The distance of about 3 mm is not considered to be patentable because Applicants have not disclosed that about 3 mm of smoothness provides some advantage, is used for a particular purpose, or solves a stated problem over smoothnesses of different distances. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well depending upon where it was implanted.

Claims 11-16, 22, 24, 25, 27-33, 36-49, and 54-56 are rejected under 35 U.S.C. 102(b) as anticipated by Schulte et al (article published 1992) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schulte et al (article published 1992). Schulte et al anticipates the claim language wherein the irregularities are 2 to 5 microns high and substantially uniform; see the whole document, especially Figure 14 and its caption. The Examiner posits that the oxide layer, if any, would be substantially removed to the extent required.

Alternatively, since the claims are set forth in the peculiar product-by-process format, it is not clear whether the Schulte et al device is identical or only substantially identical as to that claimed. However, the Examiner posits that the Schulte et al device at least clearly obviates the claimed invention because it appears to be at least substantially identical thereto; see MPEP 2113 which is incorporated herein by reference thereto.

#### ***Response to Arguments***

Applicant's arguments filed April 29, 2002 have been considered but they are not persuasive.

In response to the Applicants' argument that the "substantially" objection should be withdrawn, it is the Examiner's position that since there is a lack of guidance in this regard, it would not be proper to withdraw the rejection. This is due to the fact that the case law is relatively clear as to what is required and the present disclosure falls short of that standard.

The Applicants argue that Figure 1 of the present specification shows a substantially uniform texture while Figure 3 does not. However, the line between the two has not been made clear. It is not clear whether device with a smaller area than that shown in Figure 3 would constitute a substantially uniform texture.

In response to the argument that examples are given Examples 1 and 2 as to what constitutes substantial removal of the oxide layer and what constitutes substantially uniform irregularities, the Examiner posits that the substantial terminology is not used therein. It is noted that even Figure 3 of the parent case (US 5,876,453) has substantial removal of native oxide and a substantially uniform surface; see the language of Example 2. In fact, the disclosure thereof admits that the areas where oxides are not removed have a uniformly irregular surface. For this reason, the Examiner posits that Figure 3 thereof falls within the meaning of substantially uniform irregularities with substantially all the oxide layer removed. This is due to the broadening nature of "substantially."

In response to the traversal of the Haruyuki rejection, the Applicant argues that the topography thereof is different based upon a comparison the micrographs. This is not persuasive because the claim language does not claim any of these alleged

distinctions. For this reason, the Examiner concluded that the micrograph of Haruyuki's device falls within the claim scope.

Next, Applicants argue that Schulte is also vague and they cannot determine what is disclosed. In response, the Examiner posits that Schulte is sufficiently clear such that one can make a determination as to what is disclosed thereby. In particular, the claims of the present application are broadly recited with "substantially" and in product-by-process format such that they are read on by what is disclosed by Schulte. It appears that Applicants are reading more into the claims than is actually there.

The declaration under 37 CFR 1.132 filed June 30, 2003 is insufficient to overcome the rejection of the rejected claims based upon Haruyuki and Schulte as set forth in the last Office action because:

In the comparison of the Haruyuki device (Exhibit B) and the Applicant's device (Exhibit A), the alleged unexpected and unobvious results are not commensurate with the scope of the claims; see MPEP 716.02(d). The entire claimed range must be included in the comparison for showing unexpected results. In particular, the present claims are much broader than the one example of the present invention. For this reason, the Examiner concluded that the Haruyuki device falls within the claim scope.

Furthermore, there was no nexus between the claimed invention and the embodiment set forth in the Rule 132 declaration. Evidence of secondary considerations must be relevant to the subject matter claimed; see MPEP 716.01(b).

Finally, the unexpected results must be objective and unobvious; see MPEP 716.01(d). In the present case, the results are base upon appearance and what

Art Unit: 3738

constitutes substantially uniform and what constitutes cone-shaped. Such comparisons are extremely subjective and do not constitute actual proof or clear evidence.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
Art Unit 3738